

**REMARKS**

Claims 1-45 are pending in the present application. However, claims 24-45 have been withdrawn from consideration. Claims 1, 4, 6, 13 and 16 have been amended by way of this Amendment. Claims 2 and 7 have been cancelled and new claims 46 and 47 have been added.

**Objection to Specification**

In response to the Examiner's objection to the specification, Applicants have amended paragraph [0086] to replace "B" with "30B."

**Objection to Claims**

In response to the Examiner's objection to the claims, Applicants have amended claim 16 to delete an unnecessary semicolon.

**Rejection of Claim 6 under 35 USC §112**

In response to the rejection of claim 6 under 35 USC §112, Applicants have amended claim 6 to replace the term "implantable configuration" with the term "delivery configuration." The term "delivery configuration" has a proper antecedent basis. To improve consistency and readability, Applicants have also amended claims 1 and 4 to use the term "remodeling configuration."

**Rejection of Claims 1-3, 5-9, 11 and 12 under 35 USC §103(a)**

Claims 1-3, 5-9, 11 and 12 are rejected under 35 USC §103(a) as being unpatentable over Vidlund et al. (USPAP 2003/0130731) in view of Adams et al. (USPAP 2003/0083538). The Examiner asserts that Vidlund et al. discloses a medical device for remodeling a mitral valve annulus adjacent to the coronary sinus with all the elements of claim 1. However, the Examiner concedes that Vidlund et al. is silent to the second curve being concave in a second direction. The Examiner then asserts that Adams et al. teaches a device having a "w" configuration implanted into the coronary sinus, wherein a force is applied to a discrete portion of the atrial wall of the coronary sinus in order to reshape the mitral valve annulus for treating dilated cardiomyopathy. Finally, the Examiner asserts that it would have been obvious to one of

ordinary skill in the art to look to the teachings of Adams et al. to modify the device of Vidlund et al. such that the final shape of the device is of a "w."

Applicants respectfully assert that it would not have been obvious at the time of the invention to combine the teachings of Vidlund et al. with the teachings of Adams et al. to provide the claimed invention. Vidlund et al. (as shown in Figures 4h and 4i) merely teaches a frame member (110h) in combination with an actuation mechanism (90). The actuation mechanism is pulled proximally for causing the frame member to change its shape for creating a single continuous curve, as shown in Figure 4i. Adams et al. (as shown in Figure 3) teaches a mitral valve device (50) formed from a shape memory material. The mitral valve device includes a pair of outwardly curved end portions (52, 54) that substantially continuously engage the pericardial (outer) wall (13) of the coronary sinus. The device also includes an inwardly curved portion (56) for applying a force to a localized discrete portion of the atrial (inner) wall of the coronary sinus. Adams et al. teaches the use of friction fit or shape memory materials to achieve the curved configuration after delivery. Adams et al. provides no teaching or suggestion regarding how to use a forming element to transform the device from a delivery configuration to a remodeling configuration. Accordingly, a person of ordinary skill in the art would have no motivation to combine the structures of Vidlund et al. and Adams et al.

Although Applicants believe that independent claim 1 is allowable as originally filed, Applicants have amended claim 1 to expedite allowance of the pending claims. Claim 1 now recites a medical apparatus wherein the elongate body in the remodeling configuration comprises proximal and distal segments which are each concave in a first direction and a central segment which is concave in a second direction. Furthermore, claim 1 now recites that, at least in the remodeling configuration, the forming element extends outside the body along the central segment. Applicants note that neither reference teaches or suggests a forming element that extends outside the body along the central segment while in the remodeling configuration. In contrast, Figure 4i of Vidlund et al. illustrates a forming element that is contained entirely within the body while the device is in the remodeling configuration.

For at least the reasons discussed above, the combination of Vidlund et al. and Adams et al. cannot support a rejection of claim 1 under 35 U.S.C. §103(a). Accordingly, Applicants

respectfully request that the Examiner withdraw the rejections of claims 1-3, 5-9, 11 and 12 under 35 U.S.C. §103(a) based on Vidlund et al. in view of Adams et al.

**Rejection of Claims 4 and 10 under 35 USC 103(a)**

Claims 4 and 10 are rejected under 35 USC 103(a) as being unpatentable over Vidlund et al. and Adams et al. as applied to claims 1 and 8 above, and further in view of Alferness et al. (USPAP 2003/0105520). The Examiner asserts that Vidlund et al., as modified by Adams et al. discloses a medical device for remodeling a mitral valve annulus adjacent to the coronary sinus with all the elements of claim 1. However, the Examiner concedes that Vidlund et al. and Adams et al. are silent to the apparatus further comprising a lock for retaining the body in the second configuration, as required by claim 4. The Examiner also concedes that Vidlund et al. and Adams et al. are silent to the apparatus further comprising a first tissue anchor at the proximal end of the body, as required by claim 10. The Examiner then asserts that Alferness et al. teaches the missing limitations and that it would have been obvious to one of ordinary skill in the art to look to the teachings of Alferness et al. to modify the device of Vidlund et al. to provide the invention as recited in Applicants' claims 4 and 10.

As discussed above, Applicant asserts that independent claim 1 is distinguishable over the cited combination of references. Accordingly, dependent claims 4 and 10 are also distinguishable over the cited references. Therefore, Applicants respectfully request that the Examiner withdraw the rejections of claims 4 and 10 under 35 U.S.C. §103(a).

**Rejection of Claims 13-23 under 35 USC 103(a)**

Claims 13-23 are rejected under 35 USC 103(a) as being unpatentable over Vidlund et al. in view of Adams et al. and Alferness et al. (USPAP 2002/0169504). The Examiner asserts that Vidlund et al. discloses a medical device for remodeling a mitral valve annulus adjacent to the coronary sinus with all the elements of claim 13. However, the Examiner concedes that Vidlund et al. is silent to manipulation of the forming element deflecting the central section laterally with respect to at least a portion of the proximal and distal sections. The Examiner also concedes that Vidlund et al. is silent to a detachable coupling on the body for removably attaching the body to a deployment catheter, as further required by claim 13. The Examiner then

asserts that Adams et al. and Alferness et al., respectively, disclose the missing limitations and that it would have been obvious to one of ordinary skill in the art to look to the teachings of Adams et al. and Alferness et al. to modify the implant of Vidlund et al. to provide the claimed invention.

Applicants' independent claim 13 recites an improved implant device for positioning within a patient. The implant comprises an elongate flexible body having a proximal section, a central section and a distal section; a forming element extending through at least the proximal and distal sections of the body; and a detachable coupling on the body for removably attaching the body to a deployment catheter. The unique combination of components is assembled such that manipulation of the forming element causes the central section to deflect laterally with respect to at least a portion of the proximal and distal sections. The cited combination of references neither teaches nor suggests the structure recited by Applicant's independent claim 13. Applicant respectfully asserts that the Examiner's attempt to combine particular structural elements from Vidlund et al., Adams et al. and Alferness et al. to reconstruct the claimed invention is improper hindsight. As stated in *In re Gorman*, 933, F.2d 982:

It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the applicants' structure as a template and selecting elements from references to fill the gaps.

See also *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534, and *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, at 1551.

Vidlund et al. teach a deflectable body which simply curves in one direction. Adams et al. teaches a mitral valve device that uses a friction fit or is formed from a shape memory material. Neither Vidlund et al. nor Adams et al. teaches or suggests a device wherein a forming element can be manipulated to deflect a central section laterally with respect to the proximal and distal sections. Still further, neither Vidlund et al. nor Adams et al. provides any teaching or suggestion of how a forming element could be combined with an elongate body to provide the claimed invention. In contrast to the structures disclosed in the cited references, the inventors of the present application have invented an improved device that has not been heretofore

contemplated wherein a forming element may be used to selectively deflect a central section in a lateral direction.

To bring the pending claims to allowance, Applicants have amended claim 13 to clarify that manipulation of the forming element deflects the central section laterally with respect to at least a portion of the proximal and distal sections to selectively apply a compressive force along a region of tissue. Neither Vidlund et al. nor Adams et al. is capable of providing a selectively controllable force along a region of tissue between the first and second ends of the device by manipulation of a forming element. Those skilled in the art will appreciate that the claimed invention provides a substantial improvement in the field of mitral valve repair by advantageously providing the clinician with an improved device for selectively applying a compressive force along portion of a mitral valve annulus. The ability to selectively vary the lateral deflection of the central section of the elongate body (rather than merely using a shape memory material of Adams et al.) is important for achieving effective mitral valve repair. It will further be appreciated that the curving member disclosed by Vidlund et al. is not capable of applying a localized compressive force along its central section.

In summary, neither Vidlund et al. nor Adams et al. provides any teaching or suggestion of how a forming element could be combined with an elongate body to provide the invention recited in independent claim 13. Claims 14-23 recite additional features which further distinguish the claimed invention over the cited references. Therefore, Applicants respectfully request that the Examiner withdraw the rejections of claims 13-23 under 35 U.S.C. §103(a).

#### New Claims

New claims 46 and 47 have been added. Claims 46 and 47 each depends on claim 13, which is believed to be allowable. Furthermore, Applicant notes that none of the cited references teaches or suggests a rotatable coupling for producing axial movement of the forming element relative to the flexible body as recited in new claims 46 and 47.

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**Fees Due to File This Amendment**

Prior to the pending Office Action, a fee was paid for the original 45 claims, with 5 of them being independent claims. The aforementioned claim additions and cancellations have not resulted in more than the original number of claims, and thus no claim fees are believed to be due to file this amendment.

**Conclusion**

In light of the foregoing amendments to the claims and the above remarks, Applicants believe that this application is now in condition for allowance. Should the Examiner have any remaining questions, the Examiner is encouraged to contact the attorney of record at the telephone number shown below.

Respectfully submitted,

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